

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ORGANIC SEED GROWERS AND
TRADE ASSOCIATION, et al.,
Plaintiffs,

v.

MONSANTO COMPANY AND
MONSANTO TECHNOLOGY LLC,
Defendants.

Case No. 1:11-cv-2163-NRB-RLE

Jury Demanded

ECF Case

**MEMORANDUM OF LAW IN SUPPORT OF
MONSANTO COMPANY AND MONSANTO TECHNOLOGY LLC'S
MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION**

Dated: July 12, 2011

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**MEMORANDUM OF LAW IN SUPPORT OF
MONSANTO COMPANY AND MONSANTO TECHNOLOGY LLC'S
MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION**

Plaintiffs' amended complaint fails to meet the most fundamental requirement of a lawsuit in federal court: a justiciable case or controversy. Article III of the Constitution and the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a real, substantial, and immediate controversy between parties, not merely a hypothetical fight picked in order to debate a public-policy question. No such case or controversy exists in this case.

Plaintiffs—who bear the burden of establishing jurisdiction—do not allege that they have made, used, or sold any product embodying biotechnology patented by Defendants Monsanto Company and Monsanto Technology LLC (“Monsanto”), or that they desire to do so. Nor do Plaintiffs allege that Monsanto has contacted any of them about its patent rights, much less asserted any claim for patent infringement against them. Indeed, as Plaintiffs' Amended Complaint itself acknowledges (Am. Compl. ¶ 158), Monsanto has publicly committed *not* to exercise its patent rights against growers whose crops might inadvertently contain trace amounts of Monsanto's patented biotechnology. Under these circumstances, Plaintiffs' allegations of patent invalidity are entirely hypothetical and insufficient to support subject-matter jurisdiction over this declaratory-judgment action.

Plaintiffs have an obvious disagreement with the policy of the United States to permit and promote agricultural biotechnology. They disagree with the judgment of the United States Patent and Trademark Office (“PTO”) that transgenic plants are patentable subject matter, and they are unhappy that government agencies such as the United States Department of Agriculture (“USDA”) have repeatedly affirmed the benefits and safety of these products. Neither the Patent Act nor the Declaratory Judgment Act, however, makes the federal courts a proper forum for

Plaintiffs' anti-biotechnology campaign. The Declaratory Judgment Act does not give courts power to issue opinions on such broad policy issues based on hypothetical disputes. The Court should dismiss Plaintiffs' Amended Complaint for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

BACKGROUND STATEMENT

A. Monsanto's Patented Biotechnology

Monsanto develops, manufactures, licenses, and sells agricultural biotechnology and agricultural chemicals. *See* Ex. A to Declaration of Carolyn Jacobs Chachkin (July 12, 2011) ("Chachkin Decl."), Monsanto Company, 2010 Form 10-K (Oct. 27, 2010); Declaration of James P. Tobin (July 12, 2011) ("Tobin Decl.") ¶¶ 5-6.¹ After investing substantial time, expense, and expertise, Monsanto developed new seed technology through the carefully controlled transfer of novel genes into crop seed. Ex. A to Chachkin Decl., Monsanto Company, 2010 Form 10-K, at 4-8, 40-41. These transgenic seeds give the resulting plants an assortment of beneficial traits, including herbicide resistance, pest resistance, increased yield potential, improved nutritional content (*e.g.*, reduction of trans-fatty acids), more efficient conversion of solar energy, and drought tolerance. *See, e.g., id.* at 4-8, 40-41; Tobin Decl. ¶¶ 7-10.

Millions of growers around the world have chosen Monsanto's biotech products because of their numerous advantages. As a recent study by the National Research Council of the National Academy of Sciences concluded, "Many adopters of [transgenic] crops have experienced either lower costs of production or higher yields, and sometimes both." *See* Ex. B to

¹ Available at <http://www.sec.gov/Archives/edgar/data/1110783/000095012310096537/c60329e10vk.htm>.

Chachkin Decl., Report in Brief, National Research Council, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, at 2 (2010).²

Transgenic crops also have significant environmental and health benefits. Monsanto's popular Roundup Ready® seeds, for example, are resistant to the herbicide glyphosate (sold or marketed by Monsanto as Roundup®), and thus allow growers to apply the herbicide after the plants have emerged from the soil without fear of killing the plants themselves. See Ex. A to Chachkin Decl., Monsanto Company, 2010 Form 10-K, at 5, 7. This plant characteristic reduces or eliminates the need for farmers to till the soil, which reduces soil erosion, reduces labor and fuel costs, and conserves valuable soil moisture in drier climates. The National Research Council study cited above concluded that this reduction in tillage and associated water runoff "could represent the largest single environmental benefit of [genetically engineered] crops." Ex. B to Chachkin Decl., Report in Brief, National Research Council, at 2. Monsanto's Roundup Ready® seeds also allow growers to use safer herbicides: "the substitution enabled by genetic modifications conferring herbicide tolerance on soybeans results in glyphosate replacing other synthetic herbicides that are at least 3 times as toxic and that persist in the environment nearly twice as long as glyphosate." Ex. C to Chachkin Decl., Ralph E. Heimlich et al., *Genetically Engineered Crops: Has Adoption Reduced Pesticide Use?* 13, 17 (Aug. 2000).³ Numerous other

² Available at http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/genetically_engineered_crops_report_brief_final.pdf. Full report available at http://books.nap.edu/catalog.php?record_id=12804.

³ Available at <http://www.ers.usda.gov/publications/agoutlook/aug2000/ao273f.pdf>.

sources have recognized the environmental and societal benefits of biotech crops in general and Monsanto's products specifically.⁴

Monsanto spends over \$1 billion annually on research and development, and to protect its significant investments in these popular technologies, Monsanto relies on the patent system. Ex. A to Chachkin Decl., Monsanto Company 2010 Form 10-K, at 6, 8. Plant materials are eligible for patenting under the Patent Act, 35 U.S.C. § 101, *see J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130-31 (2001), and the PTO has granted Monsanto numerous patents covering its biotech crops and traits, as well as methods for their creation and use, *see, e.g., Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-38 (Fed. Cir. 2006) (upholding validity of Monsanto biotech patents).

Monsanto authorizes growers to use its patented biotechnology under limited-use licenses. Tobin Decl. ¶ 10. These licenses authorize growers that purchase seed containing Monsanto-patented traits to use the seed to grow a single commercial crop, but they do not allow growers to "save seed," *i.e.*, to plant the second-generation seed resulting from the original

⁴ *See, e.g.,* Ex. D to Chachkin Decl., U.S. Dep't of Agriculture, *Monsanto Company and KWS SAAT AG Supplemental Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate: Final Environmental Assessment*, at 290 (Feb. 2011) ("The adoption of herbicide-tolerant crops such as H7-1 sugar beets, glyphosate-tolerant soybeans and glyphosate-tolerant corn will result in the substitution of glyphosate for some of the previously used herbicides. ... There are known benefits associated with the use of glyphosate herbicides compared to herbicides currently used Glyphosate has documented favorable characteristics with regard to risk to human health, non-target species, and the environment."); Ex. E to Chachkin Decl., Dan Towery & Steve Werblow, Conservation Technology Information Center, *Facilitating Conservation Farming Practices and Enhancing Environmental Sustainability with Agricultural Biotechnology* 1 (2010) ("[P]lant biotechnology and the sustainable farming systems it helps facilitate ... are helping farmers grow more food, feed, fiber and fuel while protecting the environment."), *available at* <http://www.ctic.org/BiotechSustainability>; Ex. F to Chachkin Decl., Janet E. Carpenter & Leonard P. Gianessi, Nat'l Center for Food and Agricultural Policy, *Agricultural Biotechnology: Updated Benefit Estimates* 39 (Jan. 2001) ("[The] benefits of the introduction of Roundup Ready soybeans include a cost savings of \$216 million in annual weed control costs and 19 million fewer soybean herbicide applications per year.").

planting. Tobin Decl. ¶ 11. Monsanto also does not allow access to its patented biotechnology through “brown bag seed,” *i.e.*, seed that has been sold outside authorized distribution channels. *Id.* These protections are essential to Monsanto’s business, because Monsanto’s patented biotechnologies are self-replicating—the progeny of the plants grown with the novel traits will also contain those traits (and in some cases, such as soybeans, the plants reproduce at a prolific rate). Tobin Decl. ¶ 12. Without these license provisions, Monsanto’s ability to protect its patented technology would effectively be lost as soon as the first generation of the product was introduced into the market.⁵ *Id.*

Although Monsanto believes strongly in protecting its intellectual property from infringement, Monsanto has explicitly stated its commitment not to take legal action against growers whose crops might inadvertently contain traces of Monsanto biotech genes (because, for example, some transgenic seed or pollen blew on to the grower’s land). On its website, Monsanto publishes a page entitled “Monsanto’s Commitment: Farmers and Patents,” which states: “It has never been, nor will it be, Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in [a] farmer’s fields as a result of inadvertent means.” Ex. O to Chachkin Decl., *Monsanto’s Commitment: Farmers and Patents*, available at <http://www.monsanto.com/newsviews/Pages/commitment-farmers-patents.aspx> (last visited July 11, 2011). This statement is meant to assure growers that Monsanto will not pursue a patent-infringement suit where Monsanto’s patented traits appear inadvertently (*e.g.*, through cross-pollination from nearby fields where biotech crops are grown) and thus are present only in minimal quantities.

⁵ The Federal Circuit has repeatedly upheld these license provisions for Monsanto’s biotech crops. *See, e.g., Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338-41 (Fed. Cir. 2006); *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341-43 (Fed. Cir. 2004).

Consistent with its stated policy, Monsanto has never filed a patent-infringement lawsuit against a USDA-certified organic farm or handling operation for the presence of patented traits in its certified organic operations. Tobin Decl. ¶ 16. Indeed, Monsanto believes firmly in coexistence between agricultural biotechnology and organic agriculture. Such coexistence is not only possible, but proven. Since long before the introduction of agricultural biotechnology, neighboring growers have implemented coexistence practices to maintain and preserve reproductively compatible crops with different genetic traits.⁶ During the last 15 years, biotech and organic crops have successfully coexisted, with both the biotech and the organic industries growing steadily and significantly.⁷

⁶ Field corn and popcorn, for example, are capable of cross-pollinating, and each has genetic traits that would damage the other crop's value if permitted to commingle. Yet farmers commonly plant field corn and popcorn in the same geographic regions by employing cooperative management techniques that allow coexistence. *See, e.g.*, Tobin Decl. ¶ 14; Ex. G to Chachkin Decl., B. Rosie Lerner & Michael N. Dana, *Growing Sweet Corn* (May 2001), available at <http://www.hort.purdue.edu/ext/HO-98.pdf>; *see generally* Ex. H to Chachkin Decl., Declaration of Cindy J. Smith, Administrator of USDA Animal and Plant Health Inspection Service, filed in *Center for Food Safety, et al., v. Thomas J. Vilsack, et al.*, No. 3:08-cv-484-JSW (N.D. Cal.), Dkt. No. 277 (Feb. 12, 2010), at 7 ("For decades growers have successfully cultivated crops bearing different traits, often on adjoining fields, whether such traits were introduced into the crops by conventional means or genetic engineering. Growers have always had the choice of which crops to grow, and they have had to contend with commingling, admixtures, and other contaminants in their crops. Studies of coexistence of major GE and non-GE crops in North America and the European Union (E.U.) have demonstrated that there has been no significant gene flow from GE crops and that GE and non-GE crops are coexisting with minimal adverse economic effects.") (citations omitted).

⁷ *See* Ex. I to Chachkin Decl., U.S. Dep't of Agriculture, Economic Research Service, *Organic Production Data Set* ("Organic farming has been one of the fastest growing segments of U.S. agriculture for over a decade. The U.S. had under a million acres of certified organic farmland when Congress passed the Organic Foods Production Act of 1990. By the time USDA implemented national organic standards in 2002, certified organic farmland had doubled, and doubled again between 2002 and 2005."), available at <http://www.ers.usda.gov/Data/Organic/> (last visited July 11, 2011).

B. Federal Regulation of Agricultural Biotechnology and Organic Food Production

In 1986, the President's Office of Science and Technology Policy established a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products." See Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23302, 23302 (June 26, 1986).⁸ Through this coordinated framework, the USDA's Animal and Plant Health Inspection Service works in conjunction with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to analyze the health and environmental impacts of biotech crops, as well as their impact on other growers (including organic growers). See Ex. K to Chachkin Decl., U.S. Dep't of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services, *Coordinated Framework for the Regulation of Biotechnology*, Program Aid No. 1862, at 2-3 (April 2006) ("Together, [the USDA, EPA, and FDA] ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment.").⁹

The USDA specifically regulates agricultural biotechnology under the Plant Protection Act, 7 U.S.C. § 7701 *et seq.* In that regulatory capacity, USDA has consistently concluded that safe and sustainable coexistence among organic, conventional, and biotech agriculture is possible and should be promoted. See, e.g., Ex. J to Chachkin Decl., U.S. Dep't of Agriculture, *Record of Decision: Glyphosate-Tolerant Alfalfa Events n01 and J163: Request for Nonregulated Status 4* (Jan. 27, 2011) ("[T]he USDA values and promotes coexistence ... [and its] purpose and need is

⁸ Available at http://usbiotechreg.nbio.gov/read_file.nbio.

⁹ Available at http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_CoordFrameBro.pdf; accord Smith Decl., *supra*, at 4.

to promote programs that support coexistence of all types of agricultural practices,” including biotech, conventional, and organic).¹⁰

The USDA also regulates organic agriculture under the Organic Food Production Act, 7 U.S.C § 6501 *et seq.*, and through the USDA’s National Organic Program, which regulates growers that wish to market agricultural products as organically produced. The USDA has specifically considered the issue of “genetic drift,” and under the USDA’s regulations, the inadvertent presence of biotech traits in crops does not prevent organic certification. As long as organic farms follow the appropriate growing processes, “the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.” National Organic Program, 65 Fed. Reg. 80548, 80556 (Dec. 21, 2000); *id.* at 80632 (“[T]hese regulations do not establish a ‘zero tolerance’ standard” for the presence of biotech traits or material.). The USDA affirmed this position as recently as April 15, 2011. *See* Ex. L to Chachkin Decl., Policy Memorandum, U.S. Dep’t of Agriculture, at 2 (Apr. 15, 2011) (“If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a genetically modified organism alone does not constitute a violation of this [organic certification] regulation.”).¹¹ In fact, according to the USDA, no grower has ever lost organic certification as a result of inadvertent presence of transgenic material. *See* Ex. M to Chachkin Decl., Letter from U.S. Dep’t of Agriculture Under Secretary Bill Hawks to Gus Douglass, Nat’l Assn. of State Dep’ts of Agriculture, at 3 (Dec. 21, 2004).¹²

¹⁰ Available at http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_rod.pdf.

¹¹ Available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090396>.

¹² Available at <http://www.co.lake.ca.us/Assets/BOS/GE+Crops+Committee/USDA+Letter.pdf>.

C. The Plaintiffs' Amended Complaint

According to their Amended Complaint,¹³ Plaintiffs are a collection of farms, farmers, seed businesses, and agricultural organizations that engage in and support organic and conventional agriculture. Am. Compl. ¶¶ 2, 11-97. Plaintiffs allege that they “do not want to use or sell transgenic seed” in their fields and handling operations. Am. Compl. ¶ 2. Nevertheless, Plaintiffs bring the present lawsuit for a declaratory judgment because they “fear” that “if they do [] become contaminated by transgenic seed,” they “could” potentially be accused of patent infringement by Monsanto at some point in the future. Am. Compl. ¶ 2; *see also id.* ¶¶ 62, 96 (Plaintiffs are “fearful that they could become contaminated by Defendants’ transgenic seed and then be accused by Defendants of patent infringement.”).

Plaintiffs do not allege that Monsanto’s transgenic traits have actually entered their crops or seeds by gene flow or other inadvertent means. They likewise do not allege that Monsanto has ever contacted any of them, much less threatened suit, in connection with Monsanto’s patents. Further, Plaintiffs do not allege that Monsanto has ever (1) identified any patent (or claim) to any Plaintiff; (2) identified any of Plaintiffs’ products or conduct as potentially infringing Monsanto’s patents or violating its license terms, or (3) demanded royalty payments from Plaintiffs. Nor, in fact, has Monsanto done so. Indeed, Monsanto has no information suggesting that Plaintiffs’ farming activities infringe its patents.

Rather, Plaintiffs’ alleged fear of suit stems solely from Monsanto’s alleged “investigation, accusation and litigation of patent infringement claims against *other* farmers who [allegedly] did not want to be contaminated by transgenic seed.” Am. Compl. ¶ 133 (emphasis

¹³ Plaintiffs filed their original Complaint on March 29, 2011, and their Amended Complaint on June 1, 2011.

added). Plaintiffs also claim that the unintended presence of Monsanto's biotech traits may result in a "loss of USDA NOP Organic Certification" (Am. Compl. ¶¶ 11, 107), despite the USDA's clear statements to the contrary.

Plaintiffs' Amended Complaint seeks a broad declaration that each of 23 separate Monsanto biotechnology patents are invalid, unenforceable, and not infringed for a laundry list of reasons. They allege virtually every possible defense to patent infringement and every possible ground for invalidating a patent under the Patent Act —*i.e.*, unpatentable subject matter under Section 101; anticipation, obviousness, and double-patenting under Sections 102 and 103; failure to satisfy the requirements of written description, enablement, and best mode under Section 112; non-infringement due to exhaustion and lack of intent to infringe; unenforceability due to patent misuse, equitable estoppel, prosecution laches, and trespass; and non-entitlement to any remedy. Am. Compl. ¶¶ 144-183. Plaintiffs provide little or no detail on any of these claims. Plaintiffs, for example, allege that every single claim of each of the 23 Monsanto patents—more than 600 claims in total—is invalid as anticipated, obvious, or for failing to satisfy the requirements of written description, enablement, and best mode (under 35 U.S.C. §§ 102, 103, and 112), but Plaintiffs cite no prior art and fail to give any further explanation. Am. Compl. ¶¶ 168-69. Plaintiffs' primary argument appears to be that all of Monsanto's patents are invalid under 35 U.S.C. § 101 for failing to be "useful." *See* Am. Compl. ¶¶ 4, 101-125, 144.

ARGUMENT

I. PLAINTIFFS CANNOT SHOW A REAL, SUBSTANTIAL, AND IMMEDIATE DISPUTE BETWEEN THE PARTIES AND THEREFORE CANNOT ESTABLISH SUBJECT-MATTER JURISDICTION

Plaintiffs have no basis to contend that Monsanto might ever sue them for patent infringement. Plaintiffs do not allege that Monsanto has had any contact with them regarding patent infringement or has suggested in any forum that it might take legal action against them. Moreover, Plaintiffs expressly disclaim any intent to plant transgenic crops. Monsanto knows of no basis to sue Plaintiffs, and has no interest in doing so.

Plaintiffs, however, oppose agricultural biotechnology, and they are attempting to pick a fight with Monsanto by asking this Court to declare that 23 Monsanto biotechnology patents are invalid, unenforceable, and not infringed—a result that, paradoxically, would likely *increase* the use of Monsanto’s biotechnology, which would then be freely available without patent-law restrictions.

Article III of the Constitution and the Declaratory Judgment Act do not permit federal courts to exercise jurisdiction over such abstract policy debates. Under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), and the Federal Circuit’s case law interpreting *MedImmune*, a declaratory-judgment action requires a real, substantial, and immediate case or controversy. There is no such case or controversy here.

In *MedImmune*, the Supreme Court explained that an Article III case or controversy must “be ‘definite and concrete, touching the legal relations of parties having adverse legal interests’”; and “be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’” *MedImmune*, 549 U.S. at 127 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). Thus, “all the

circumstances” must demonstrate “a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Id.*

Such a controversy requires at least two parties, and under Federal Circuit precedent, the conduct of both parties is relevant in evaluating “all the circumstances.” The conduct of the declaratory-judgment plaintiff must create a real, immediate, and substantial potential for infringement, and the conduct of the patentee must create a real, immediate, and substantial potential for a claim of infringement against the declaratory-judgment plaintiff. Without such activity by both parties, there is no real, immediate, and substantial controversy between parties, but only a hypothetical, potential, and indefinite dispute. *See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (*MedImmune* “did not change the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the [declaratory-judgment] defendants*”) (emphasis in original); *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008) (test for justiciability “looks to the [declaratory-judgment plaintiff’s] conduct and ensures that the controversy is sufficiently real and substantial” (citation omitted)).

Thus, following *MedImmune*, the Federal Circuit has held that subject-matter jurisdiction requires at least: (1) an affirmative act by the patentee directed toward the declaratory-judgment plaintiff; and (2) current activity by the declaratory-judgment plaintiff that could constitute infringement or significant, concrete steps toward conducting infringing activity. *See Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir.), *cert. denied*, 131 S. Ct. 424 (2010); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 n.4 (Fed. Cir. 2008);

Cat Tech, 528 F.3d at 880; *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343-44 (Fed. Cir. 2007).

Moreover, Plaintiffs bear the burden of proving the existence of a justiciable controversy at the time they initiated this lawsuit on March 29, 2011. *See Innovative Therapies*, 599 F.3d at 1382-84; *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1345 (Fed. Cir. 2010); *Benitec*, 495 F.3d at 1344. And Plaintiffs' purported bases for declaratory-judgment jurisdiction "should be found in the complaint." *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 576 n.8 (Fed. Cir. 1986).

Plaintiffs here provide no allegations of (1) any action by Monsanto directed toward Plaintiffs; or (2) any potentially infringing conduct or concrete steps toward infringing conduct sufficient to create a "real" and "immediate" controversy. Accordingly, this case should be dismissed for lack of subject-matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

A. Monsanto Has Taken No Action Toward Plaintiffs To Create a Real, Substantial, and Immediate Dispute

"[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, *without some affirmative act by the patentee.*" *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) (emphasis added). In particular, it is a "bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is *caused by the [declaratory-judgment] defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco*, 537 F.3d at 1339 (emphasis in original; other emphasis omitted). Thus, the Federal Circuit has required that the patentee have taken some targeted action *toward a current*

declaratory-judgment plaintiff. See *Innovative Therapies*, 599 F.3d at 1382; *Creative Compounds, LLC v. Starmark Labs.*, --- F.3d ---, 2011 WL 2519513, at *10-12 (Fed. Cir. June 24, 2011). Because the Amended Complaint fails to allege *any* affirmative act by Monsanto directed toward Plaintiffs, Plaintiffs fail to establish declaratory-judgment jurisdiction.

1. Monsanto has not taken *any* affirmative action toward Plaintiffs, much less action that could be construed as causing a “real and immediate injury or threat of future injury”

Although they purport to harbor “fears” that Monsanto may “accuse[]” them of patent infringement, Am. Compl. ¶¶ 3, 96, Plaintiffs allege no action by Monsanto that could be interpreted as causing or threatening a “real and immediate” injury. Plaintiffs do not contend that Monsanto has ever identified any patent (or any claim thereof) to any Plaintiff, as the declaratory defendant did in *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1362-63 (Fed. Cir. 2009). Nor do they contend that Monsanto has identified any of Plaintiffs’ products or conduct as potentially infringing its patents or violating the terms of its licenses, as the patentees did in *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348-49 (Fed. Cir. 2011), and *Hewlett-Packard*, 587 F.3d at 1362-63. Plaintiffs likewise do not contend that Monsanto has ever demanded royalty payments (or asserted any rights to receive such payments) from Plaintiffs. Cf. *MedImmune*, 549 U.S. 121-22; *SanDisk*, 480 F.3d at 1382; see also *Prasco*, 537 F.3d at 1339. Plaintiffs do not even contend that Monsanto has *at any time* initiated any visit, call, or correspondence with Plaintiffs in connection with Monsanto’s patents.

In short, Plaintiffs do not—and cannot—point to any activity whatsoever, let alone any threat of legal liability, by Monsanto toward any of these Plaintiffs. As such, there is no “real and immediate” injury or threat of injury sufficient to create declaratory-judgment jurisdiction. See *Prasco*, 537 F.3d at 1340, 1342 (declaratory-judgment plaintiff failed to establish imminent

risk of injury, where there was a “lack of any evidence that the defendants believe[d] or plan[ned] to assert” that plaintiff infringed their patents).

Plaintiffs cannot rely solely on Monsanto’s litigation efforts against *different* entities. Any such litigation would hardly create a “real and immediate” injury or threat of injury against Plaintiffs, who constitute only a small fraction of the 2 million farms in the United States.¹⁴ Indeed, the Federal Circuit has held that a patent owner’s efforts to enforce its legal rights with respect to *other* parties cannot establish an actual controversy in the absence of an affirmative act directed against *the present declaratory-judgment plaintiff(s)*. See *Innovative Therapies*, 599 F.3d at 1382 (patentee’s filing of infringement suits against other parties “does not, in the absence of any act directed toward [declaratory judgment plaintiff], meet the minimum standard discussed in *MedImmune*.”). Just last month, the Federal Circuit reversed a district court that found subject-matter jurisdiction where the patentee took no action directed toward the declaratory-judgment plaintiff. See *Creative Compounds, LLC v. Starmark Labs.*, --- F.3d ---, 2011 WL 2519513, at *10-12 (Fed. Cir. June 24, 2011). Even though the patentee had sent infringement letters to others in the industry, including the declaratory-judgment plaintiff’s purported customers, that was not sufficient to create an actual controversy between the patentee and the declaratory-judgment plaintiff. *Id.* at *11 (“Here, [the patentee] never accused [the declaratory-judgment plaintiff] of infringing its ’273 Patent. While [the patentee] did send letters to purchasers of [the product] alleging that [product] would infringe claims of the ’273 Patent, none of these letters were sent to [declaratory-judgment plaintiff].”).

¹⁴ See Ex. N to Chachkin Decl., U.S. Environmental Protection Agency, *Demographics*, at <http://www.epa.gov/agriculture/ag101/demographics.html> (last visited July 11, 2011); see also Ex. I to Chachkin Decl., U.S. Dep’t of Agriculture, Economic Research Service, *Organic Production Data Set* (“[C]ertified organic cropland and pasture accounted for about 0.6 percent of U.S. total farmland in 2008.”), available at <http://www.ers.usda.gov/Data/Organic/>.

2. Monsanto has not taken any position adverse to Plaintiffs in connection with the named patents

Monsanto and Plaintiffs also do not have “adverse legal interests” as required under *MedImmune* to establish a justiciable case or controversy. As the Federal Circuit has observed, “[t]he [declaratory] defendants’ lack of any ‘concrete claim of a specific right’ [against the declaratory plaintiff] is an important factor weighing against a finding of an actual controversy, particularly [where] [] there has been no actual injury.” *Prasco*, 537 F.3d at 1340 & n.8 (no declaratory-judgment jurisdiction where defendants had “not taken a concrete position adverse to” plaintiff’s, and plaintiff failed to show “which if any of [four referenced patents and 71 referenced claims] defendants could or might assert”).

Plaintiffs here fail to establish that Monsanto has taken any concrete position adverse to Plaintiffs. Indeed, the only position Monsanto has taken is its general public commitment *not* to pursue legal action against growers who might inadvertently have trace amounts of a patented trait. As explained above, Monsanto publishes on its website its “Monsanto’s Commitment: Farmers and Patents,” which affirmatively states: “It has never been, nor will it be, Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in [a] farmer’s fields as a result of inadvertent means.” Ex. O to Chachkin Decl., *Monsanto’s Commitment: Farmers and Patents*, available at <http://www.monsanto.com/newsviews/Pages/commitment-farmers-patents.aspx>. Consistent with this policy, Monsanto has *never* filed a patent-infringement lawsuit against a USDA-certified organic farm or handling operation for the presence of patented traits in its certified organic operations. Tobin Decl. ¶ 16.

Thus, Monsanto is unaware of any circumstances that would give rise to any claim for patent infringement or any lawsuit against any of the Plaintiffs. Although Plaintiffs try to

conjure up a specter of Monsanto adversely threatening litigation against defenseless organic farmers, that fear simply has no basis in reality.¹⁵

B. Plaintiffs Have Not Alleged Any Potentially Infringing Conduct by Plaintiffs or Steps Toward Such Conduct Sufficient To Create an “Immediate” Or “Real” Controversy

Even apart from the absence of any affirmative act by Monsanto directed toward the Plaintiffs, the Amended Complaint should be dismissed because Plaintiffs fail to allege any potentially infringing conduct on their part, or even meaningful preparation toward potentially infringing conduct. “A party may not ‘obtain a declaratory judgment merely because it would like an advisory opinion on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity.’” *Cat Tech*, 528 F.3d at 881 (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)). Rather, an “immediate” and “real” controversy requires a declaratory-

¹⁵ Nor does the post-lawsuit, April 2011 letter exchange between the parties’ counsel (see Am. Compl. ¶¶ 139-43) provide any basis for jurisdiction. First, the existence of a justiciable case or controversy depends on the state of affairs when the original claim for declaratory relief was filed. See *Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 570-71 (2004). “[L]ater events may not create jurisdiction where none existed at the time of filing.” *Innovative Therapies*, 599 F.3d at 1383-84 (citing *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996)). Plaintiffs’ April 18 letter in fact acknowledges the lack of declaratory-judgment jurisdiction on March 29 when the original Complaint was filed: the letter notes that “[i]f” Monsanto did not respond to the letter, “[i]t would then be reasonable for our clients to feel they would be at risk of having Monsanto assert claims of patent infringement.” Am. Compl., Ex. 3 at 1-2 (emphasis added).

Second, courts have condemned ploys by declaratory-judgment plaintiffs to gin up a case or controversy where none otherwise existed by contacting patentees to bait them into making some statement acknowledging a potential claim. See *Innovative Therapies*, 599 F.3d at 1384-85.

Finally, and contrary to Plaintiffs’ distorted version of events (Am. Compl. ¶¶ 139-43), Monsanto’s April 28 responsive letter clearly and unambiguously disavows any intent or basis to sue the Plaintiffs. See Am. Compl., Ex. 4 (“Monsanto is unaware of any circumstances that would give rise to any claim for patent infringement or any lawsuit against your clients. Monsanto therefore does not assert and has no intention of asserting patent-infringement claims against your clients.”).

judgment plaintiff to show it has either (1) engaged in the “actual manufacture or sale of a potentially infringing product” or (2) conducted “meaningful preparation” toward potentially infringing activity. *Cat Tech*, 528 F.3d at 881; *see also Benitec*, 495 F.3d at 1348-49. Where it is “uncertain when, if ever, the declaratory plaintiff would engage in potentially infringing activity, the dispute d[oes] not present a case or controversy of sufficient immediacy to support a declaratory judgment.” *Cat Tech*, 528 F.3d at 881; *see also Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004) (the greater the length of time before potentially infringing activity is expected to occur, “the more likely the case lacks the requisite immediacy.”).

Here, Plaintiffs allege that they desire to *avoid* any presence of Monsanto’s patented biotechnology traits in their crops. The Amended Complaint specifically alleges that “Plaintiffs do not intend to use Monsanto’s transgenic seed” and generally “do not want to use or sell [any] transgenic seed.” Am. Compl. ¶¶ 2, 5.

To be sure, Plaintiffs suggest that the *unintentional* presence of Monsanto’s patented traits on their fields (through cross-pollination or other means) could cause them to infringe. But Plaintiffs do not allege that inadvertent gene flow creates a substantial or imminent risk of infringement. They do not recite a single instance—or name a single Plaintiff’s farm or business—where such “contamination” has occurred. Nor do they express when, if ever, it might occur. Indeed, the Amended Complaint is devoid of any specific facts to support an inference that any plaintiff will *ever* inadvertently infringe. Instead, Plaintiffs offer only the most generalized allegations about the “contaminating character of transgenic seed.” Am. Compl. ¶ 62. Such vague speculation about the future does not establish an immediate, real, or substantial potential for infringement and

cannot satisfy Article III and the Declaratory Judgment Act. *See Benitec*, 495 F.3d at 1346-47 (no declaratory-judgment jurisdiction because it was uncertain when, if ever, the declaratory plaintiff would engage in potentially infringing activity); *Sierra*, 363 F.3d at 1378-80; *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525-27 (Fed. Cir. 1992) (affirming dismissal where device was years away from any release); *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 763-65 (Fed. Cir. 1990) (affirming dismissal where product would not be finished until at least 9 months after complaint was filed).

Unable to identify any evidence of an actual, concrete dispute with Monsanto, Plaintiffs resort to allegations concerning their mere subjective apprehensions of “contamination” and litigation at some unspecified future date. *See, e.g.*, Am. Compl. ¶ 3 (discussing “Plaintiffs’ fears” that they will be accused of patent infringement “if and when they become contaminated” in the “future”); *id.* ¶ 62 (alleging Plaintiffs are “fearful that they could become contaminated” and “then be accused” of infringement); *id.* ¶ 96 (same). But such assertions again cannot establish jurisdiction under Article III and the Declaratory Judgment Act, which require a “real and immediate” controversy—an “objective” determination “that cannot be met by a purely subjective or speculative fear of future harm.” *Prasco*, 537 F.3d at 1339; *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (“It is the *reality* of the threat of [] injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehensions. The emotional consequences of a prior act simply are not a sufficient basis for an injunction absent a real and immediate threat of future injury by the defendant.”) (emphasis in original).

* * * * *

Plaintiffs have no actual basis to allege either that they would ever infringe any of Monsanto's patents, or that Monsanto would ever sue them for doing so. Plaintiffs say they do not want to grow crops containing Monsanto's technology, and Monsanto has no reason, desire, or intent to sue them.

Plaintiffs clearly have firmly held views about the propriety of biotechnology, but they have no ground on which to invoke the jurisdiction of the federal courts to advocate those views. The constitutional requirement of a case or controversy "tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action. ... The federal courts have abjured appeals to their authority which would convert the judicial process into no more than a vehicle for the vindication of the value interests of concerned bystanders." *Valley Forge Christian Coll. v. Americans United For Separation of Church and State*, 454 U.S. 464, 472-73 (1982) (internal quotation marks omitted). Because

Plaintiffs' Amended Complaint raises no case or controversy, it should be dismissed for lack of jurisdiction.

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Respectfully submitted,

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